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AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

LOUISE KLEFT and BILL KREFT,
Plaintiffs,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
and G.D. SEARLE LLC,

Defendants.

) MDL Docket No. 1699
)
) CASE NO. 3:07-cv-4744-CRB
)
) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE LLC'S ANSWER TO**
) **COMPLAINT**
)
) **JURY DEMAND ENDORSED**
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC
3 (Improperly captioned in Plaintiffs' Complaint as "G. D. Searle LLC (f/k/a G.D. Seabee &
4 Co.)") ("Searle"), (collectively "Defendants") and file this Answer to Plaintiffs' Complaint
5 ("Complaint"), and would respectfully show the Court as follows:

6 **I.**

7 **PRELIMINARY STATEMENT**

8 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
9 Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted
10 generally. Defendants may seek leave to amend this Answer when discovery reveals the
11 specific time periods in which Plaintiff was prescribed and used Celebrex®.

12 **II.**

13 **ANSWER**

14 Answering the unnumbered paragraph preceding Paragraph 1 of the Complaint,
15 Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but deny
16 that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain
17 periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United
18 States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
19 accordance with their approval by the FDA. Defendants admit that, during certain periods of
20 time, Celebrex® was manufactured and packaged for Searle, which developed, tested,
21 marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by
22 healthcare providers who are by law authorized to prescribe drugs in accordance with their
23 approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used
24 in accordance with its FDA-approved prescribing information. Defendants state that the
25 potential effects of Celebrex® were and are adequately described in its FDA-approved
26 prescribing information, which was at all times adequate and comported with applicable
27 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused
28 Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the

1 Complaint.

2 **Response to Allegations Regarding Parties**

3 1. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' age, citizenship,
5 and marital status, and, therefore, deny the same. Defendants deny the remaining allegations in
6 this paragraph of the Complaint.

7 2. Defendants admit that Pfizer is a Delaware corporation with its principal place of
8 business in New York. Defendants admit that, as the result of a merger in April 2003,
9 Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph
10 of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants
11 are without knowledge or information sufficient to form a belief as to the truth of such
12 allegations, and, therefore, deny the same. Defendants admit that, during certain periods of
13 time, Pfizer marketed and co-promoted Celebrex® in the United States, including North
14 Dakota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs
15 in accordance with their approval by the FDA. Defendants deny the remaining allegations in
16 this paragraph of the Complaint.

17 3. Defendants admit that Searle is a Delaware limited liability company with its principal
18 place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that,
19 as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
20 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
21 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
22 Celebrex® in the United States to be prescribed by healthcare providers who are by law
23 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
24 the remaining allegations in this paragraph of the Complaint.

25 4. Defendants admit that Pharmacia is a Delaware corporation with its principal place of
26 business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as
27 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
28 Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted

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1 Celebrex® in the United States, including North Dakota and California, to be prescribed by
2 healthcare providers who are by law authorized to prescribe drugs in accordance with their
3 approval by the FDA. Defendants deny the remaining allegations in this paragraph of the
4 Complaint.

5 5. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
6 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
7 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
8 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
9 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
10 Celebrex® in the United States to be prescribed by healthcare providers who are by law
11 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
12 that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle
13 and Pharmacia became subsidiaries of Pfizer. Defendants deny the remaining allegations in this
14 paragraph of the Complaint.

15 6. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
16 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
17 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
18 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
19 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
20 Celebrex® in the United States to be prescribed by healthcare providers who are by law
21 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state
22 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
23 prescribing information. Defendants state that the potential effects of Celebrex® were and are
24 adequately described in its FDA-approved prescribing information, which was at all times
25 adequate and comported with applicable standards of care and law. Defendants deny any
26 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

27 7. Defendants state that the allegations in this paragraph of the Complaint regarding
28 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or

1 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny
2 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

3 **Response to Allegations Regarding Jurisdiction and Venue**

4 8. Defendants are without knowledge or information to form a belief as to the truth of the
5 allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and the amount
6 in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiffs claim
7 that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of
8 interests and costs.

9 9. Defendants are without knowledge or information to form a belief as to the truth of the
10 allegations in this paragraph of the Complaint regarding the judicial district in which the
11 asserted claims allegedly arose and, therefore, deny the same. Defendants state that Celebrex®
12 was and is safe and effective when used in accordance with its FDA-approved prescribing
13 information. Defendants deny committing a tort in the State of North Dakota or the State of
14 California and deny the remaining allegations in this paragraph of the Complaint.

15 10. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
16 and co-promoted Celebrex® in the United States, including North Dakota and California, to be
17 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
18 with their approval by the FDA. Defendants admit that, during certain periods of time,
19 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
20 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
21 providers who are by law authorized to prescribe drugs in accordance with their approval by the
22 FDA. Defendants admit that Pfizer, Pharmacia, and Searle are registered to and do business in
23 the States of North Dakota and California. Defendants state that the allegations in this
24 paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous.
25 Defendants are without knowledge or information sufficient to form a belief as to the truth of
26 such allegations, and, therefore, deny the same. Defendants deny committing a tort in the State
27 of North Dakota or the State of California and deny the remaining allegations in this paragraph
28 of the Complaint.

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Response to Allegations Regarding Interdistrict Assignment

11. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac. and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005.

Response to Factual Allegations

12. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition or whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Celebrex® caused Plaintiffs injury or damage and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage and deny the remaining allegations in this

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1 paragraph of the Complaint.

2 15. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
4 Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case,
5 Celebrex® was expected to reach users and consumers without substantial change from the
6 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

7 16. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
9 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
10 effective when used in accordance with its FDA-approved prescribing information. Defendants
11 state that the potential effects of Celebrex® were and are adequately described in its FDA-
12 approved prescribing information, which was at all times adequate and comported with
13 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
14 remaining allegations in this paragraph of the Complaint.

15 17. Defendants state that the allegations in this paragraph of the Complaint regarding
16 aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no
17 response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times,
18 referred to as being non-steroidal anti-inflammatory drugs (“NSAIDs”). Defendants deny the
19 remaining allegations in this paragraph of the Complaint.

20 18. Defendants state that the allegations in this paragraph of the Complaint are not directed
21 towards Defendants and, therefore, no response is required. To the extent that a response is
22 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the
23 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
24 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

25 19. Defendants state that the allegations in this paragraph of the Complaint are not directed
26 towards Defendants and, therefore, no response is required. To the extent that a response is
27 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the
28 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information

1 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

2 20. Defendants state that the allegations in this paragraph of the Complaint are not directed
3 towards Defendants and, therefore, no response is required. To the extent that a response is
4 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the
5 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
6 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

7 21. Plaintiffs' Complaint omits Paragraph Number 21.

8 22. Defendants state that the allegations in this paragraph of the Complaint regarding "other
9 pharmaceutical companies" are not directed towards Defendants and, therefore, no response is
10 required. To the extent a response is deemed required, Defendants state that, as stated in the
11 FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to
12 be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2
13 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the
14 cyclooxygenase-1 (COX-1) isoenzyme." Plaintiffs fail to provide the proper context for the
15 remaining allegations in this paragraph and Defendants therefore lack sufficient information or
16 knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining
17 allegations in this paragraph of the Complaint.

18 23. Defendants state that the allegations in this paragraph of the Complaint regarding
19 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or
20 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny
21 the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he
22 mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,
23 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in
24 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme." Defendants
25 state that Celebrex® was and is safe and effective when used in accordance with its FDA-
26 approved prescribing information. Defendants state that the potential effects of Celebrex®
27 were and are adequately described in its FDA-approved prescribing information, which was at
28 all times adequate and comported with applicable standards of care and law. Defendants deny

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1 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

2 24. Defendants admit that Searle submitted a New Drug Application (“NDA”) for
3 Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted
4 approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of
5 osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults.
6 Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to
7 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis
8 (“FAP”) as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny
9 the remaining allegations in this paragraph of the Complaint.

10 25. Defendants admit that Celebrex® was launched in February 1999. Defendants admit
11 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted
12 Celebrex® in the United States to be prescribed by healthcare providers who are by law
13 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
14 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
15 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
16 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
17 accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe
18 and effective when used in accordance with its FDA-approved prescribing information.
19 Defendants state that the potential effects of Celebrex® were and are adequately described in its
20 FDA-approved prescribing information, which was at all times adequate and comported with
21 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
22 remaining allegations in this paragraph of the Complaint.

23 26. Defendants state that the referenced article speaks for itself and respectfully refer the
24 Court to the article for its actual language and text. Any attempt to characterize the article is
25 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
27 this paragraph of the Complaint.

28 27. Defendants state that the referenced article speaks for itself and respectfully refer the

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1 Court to the article for its actual language and text. Any attempt to characterize the article is
2 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
4 this paragraph of the Complaint.

5 28. Defendants state that the referenced FDA Update speaks for itself and respectfully refer
6 the Court to the FDA Update for its actual language and text. Any attempt to characterize the
7 FDA Update is denied. Defendants state that Celebrex® was and is safe and effective when
8 used in accordance with its FDA-approved prescribing information. Defendants state that the
9 potential effects of Celebrex® were and are adequately described in its FDA-approved
10 prescribing information, which was at all times adequate and comported with applicable
11 standards of care and law. Defendants deny the remaining allegations in this paragraph of the
12 Complaint.

13 29. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
18 the Complaint.

19 30. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA
20 on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to
21 characterize it is denied. Defendants admit that a Medical Officer Review dated September 20,
22 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself
23 and respectfully refer the Court to the study for its actual language and text. Any attempt to
24 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of
25 the Complaint.

26 31. Defendants state that the referenced article speaks for itself and respectfully refer the
27 Court to the article for its actual language and text. Any attempt to characterize the article is
28 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

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32. Plaintiffs' Complaint omits Paragraph Number 32.

33. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

34. Defendants state that the Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

35. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and respectfully refer the Court to the transcripts for their actual language and text. Any attempt to characterize the transcripts is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

36. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the articles is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

37. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

38. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the articles is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

39. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is

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1 denied. Defendants state that the referenced study speaks for itself and respectfully refer the
2 Court to the study for its actual language and text. Any attempt to characterize the study is
3 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 40. Defendants state that the referenced Medical Officer Review speaks for itself and
5 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
6 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
7 allegations in this paragraph of the Complaint.

8 41. Plaintiffs fail to provide the proper context for the allegations concerning “Public
9 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or
10 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
11 Defendants deny the remaining allegations in this paragraph of the Complaint.

12 42. Defendants state that the referenced article speaks for itself and respectfully refer the
13 Court to the article for its actual language and text. Any attempt to characterize the article is
14 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
15 paragraph of the Complaint.

16 43. Defendants state that the referenced study speaks for itself and respectfully refer the
17 Court to the study for its actual language and text. Any attempt to characterize the study is
18 denied. Plaintiffs fail to provide the proper context for the allegations concerning “Public
19 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or
20 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
21 Defendants deny the remaining allegations in this paragraph of the Complaint.

22 44. Defendants admit that there was a clinical trial called APC. Defendants state that the
23 referenced article speaks for itself and respectfully refer the Court to the article for its actual
24 language and text. Any attempt to characterize the article is denied. Defendants deny the
25 remaining allegations in this paragraph of the Complaint.

26 45. Defendants state that the referenced article speaks for itself and respectfully refer the
27 Court to the article for its actual language and text. Any attempt to characterize the article is
28 denied. Plaintiffs fail to provide the proper context for the allegations concerning “Data Safety

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1 Monitoring Board” in this paragraph of the Complaint. Defendants therefore lack sufficient
2 information or knowledge to form a belief as to the truth of such allegations and, therefore,
3 deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 46. Defendants state that the referenced article speaks for itself and respectfully refer the
5 Court to the article for its actual language and text. Any attempt to characterize the article is
6 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

7 47. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
8 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
9 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
10 Defendants deny the remaining allegations in this paragraph of the Complaint.

11 48. Defendants state that the referenced Medical Officer Review speaks for itself and
12 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
13 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
14 allegations in this paragraph of the Complaint.

15 49. Defendants admit that there was a clinical trial called PreSAP. Plaintiffs fail to provide
16 the proper context for the allegations concerning “other Celebrex trials” contained in this
17 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
18 form a belief as to the truth of such allegations and, therefore, deny the same. As for the
19 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state
20 that the referenced study speaks for itself and respectfully refer the Court to the study for its
21 actual language and text. Any attempt to characterize the study is denied. Defendants deny the
22 remaining allegations in this paragraph of the Complaint.

23 50. Defendants state that the referenced article speaks for itself and respectfully refer the
24 Court to the article for its actual language and text. Any attempt to characterize the article is
25 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

26 51. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the
27 Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants
28 therefore lack sufficient information or knowledge to form a belief as to the truth of such

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1 allegations and, therefore, deny the same. Defendants state that the referenced studies speak for
2 themselves and respectfully refer the Court to the studies for their actual language and text.
3 Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in
4 this paragraph of the Complaint.

5 52. Defendants state that the referenced Medical Officer Review speaks for itself and
6 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
7 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
8 allegations in this paragraph of the Complaint.

9 53. Defendants state that allegations regarding Vioxx® in this paragraph of the Complaint
10 are not directed toward Defendants, and therefore no response is required. To the extent that a
11 response is deemed required, Plaintiffs fail to provide the proper context for the allegations in
12 this paragraph of the Complaint regarding Vioxx® in this paragraph of the Complaint.
13 Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of
14 such allegations and, therefore, deny the same. Defendants state that the referenced study
15 speaks for itself and respectfully refer the Court to the study for its actual language and text.
16 Any attempt to characterize the study is denied. Defendants deny the remaining allegations in
17 this paragraph of the Complaint.

18 54. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
19 Complaint are not directed toward Defendants, and therefore no response is required. To the
20 extent that a response is deemed required, Plaintiffs fail to provide the proper context for the
21 allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph
22 of the Complaint. Defendants therefore lack sufficient information or knowledge to form a
23 belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the
24 referenced study speaks for itself and respectfully refer the Court to the study for its actual
25 language and text. Any attempt to characterize the study is denied. Defendants deny the
26 remaining allegations in this paragraph of the Complaint.

27 55. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
28 Complaint are not directed toward Defendants, and therefore no response is required. To the

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1 extent that a response is deemed required, Plaintiffs fail to provide the proper context for the
2 allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph
3 of the Complaint. Defendants therefore lack sufficient information or knowledge to form a
4 belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the
5 referenced study speaks for itself and respectfully refer the Court to the study for its actual
6 language and text. Any attempt to characterize the study is denied. Defendants state that the
7 referenced article speaks for itself and respectfully refer the Court to the article for its actual
8 language and text. Any attempt to characterize the article is denied. Defendants deny the
9 remaining allegations in this paragraph of the Complaint.

10 56. Defendants state that Celebrex® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants deny the allegations in this
12 paragraph of the Complaint.

13 57. Defendants state that the referenced article speaks for itself and respectfully refer the
14 Court to the article for its actual language and text. Any attempt to characterize the article is
15 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

16 58. Defendants state that allegations in this paragraph of the Complaint are not directed
17 toward Defendants, and therefore no response is required. To the extent that a response is
18 deemed required, Defendants state that the referenced article speaks for itself and respectfully
19 refer the Court to the article for its actual language and text. Any attempt to characterize the
20 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

21 59. Defendants deny the allegations in this paragraph of the Complaint.

22 60. Defendants state that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
27 remaining allegations contained in this paragraph of the Complaint.

28 61. Defendants deny any wrongful conduct and deny the allegations contained in this

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1 paragraph of the Complaint.

2 62. Defendants deny any wrongful conduct and deny the allegations contained in this
3 paragraph of the Complaint.

4 63. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct and deny the remaining allegations contained in this
9 paragraph of the Complaint.

10 64. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
12 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Celebrex® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
17 Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of
18 the Complaint.

19 65. Defendants admit that the FDA Division of Drug Marketing, Advertising, and
20 Communications (“DDMAC”) sent letters to Searle dated October 6, 1999, April 6, 2000, and
21 November 14, 2000. Defendants state that the referenced letters speak for themselves and
22 respectfully refer the Court to the letters for their actual language and text. Any attempt to
23 characterize the letters is denied. Defendants deny the remaining allegations in this paragraph
24 of the Complaint.

25 66. Defendants admit that the DDMAC sent a letter to Pharmacia dated February 1, 2001.
26 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to
27 the letter for its actual language and text. Any attempt to characterize the letter is denied.
28 Defendants deny the remaining allegations in this paragraph of the Complaint.

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1 67. Defendants state that the referenced article speaks for itself and respectfully refer the
2 Court to the article for its actual language and text. Any attempt to characterize the article is
3 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 68. Defendants admit that the DDMAC sent a letter to Pfizer dated January 10, 2005.
5 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to
6 the letter for its actual language and text. Any attempt to characterize the letter is denied.
7 Defendants deny the remaining allegations in this paragraph of the Complaint.

8 69. Defendants state that Celebrex® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
13 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
14 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
15 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
16 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
17 United States to be prescribed by healthcare providers who are by law authorized to prescribe
18 drugs in accordance with their approval by the FDA. Defendants deny the remaining
19 allegations in this paragraph of the Complaint.

20 70. Defendants state that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
25 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
26 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
27 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
28 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the

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1 United States to be prescribed by healthcare providers who are by law authorized to prescribe
2 drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a
3 prescription medication which is approved by the FDA for the following indications: (1) for
4 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of
5 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the
6 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps
7 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic
8 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for
9 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age
10 and older. Defendants deny any wrongful conduct and deny the remaining allegations in this
11 paragraph of the Complaint.

12 71. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which at all times was adequate and comported with applicable standards of care and law.
16 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
17 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
18 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
19 that Celebrex® is defective, and deny the allegations in this paragraph of the Complaint.

20 72. Defendants state that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
25 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
26 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
27 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
28 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the

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1 United States to be prescribed by healthcare providers who are by law authorized to prescribe
2 drugs in accordance with their approval by the FDA. Defendants deny the remaining
3 allegations in this paragraph of the Complaint.

4 73. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which at all times was adequate and comported with applicable standards of care and law.
8 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
9 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
10 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
11 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
12 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
13 United States to be prescribed by healthcare providers who are by law authorized to prescribe
14 drugs in accordance with their approval by the FDA. Defendants deny the remaining
15 allegations in this paragraph of the Complaint.

16 74. Defendants state that Celebrex® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
21 the Complaint.

22 75. Defendants state that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.

28 76. Defendants deny the allegations in this paragraph of the Complaint.

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1 77. Defendants state that Celebrex® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
6 the Complaint.

7 78. Defendants state that Celebrex® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
12 the Complaint.

13 79. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
15 Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that
16 Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this
17 paragraph of the Complaint.

18 80. Defendants state that Celebrex® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
23 remaining allegations in this paragraph of the Complaint.

24 81. Defendants state that Celebrex® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants state that the potential effects of
26 Celebrex® are and were adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

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1 the Complaint.

2 82. Defendants state that Celebrex® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants state that the potential effects of
4 Celebrex® are and were adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
7 the study for its actual language and text. Any attempt to characterize the study is denied.
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint.

10 83. Defendants deny any wrongful conduct and deny the remaining allegations in this
11 paragraph of the Complaint.

12 84. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
14 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
15 effective when used in accordance with its FDA-approved prescribing information. Defendants
16 state that the potential effects of Celebrex® are and were adequately described in its FDA-
17 approved prescribing information, which was at all times adequate and comported with
18 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
19 remaining allegations in this paragraph of the Complaint.

20 **Response to First Cause of Action: Negligence**

21 85. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
22 Complaint as if fully set forth herein.

23 86. Defendants state that this paragraph of the Complaint contains legal contentions to
24 which no response is required. To the extent that a response is deemed required, Defendants
25 admit that they had duties as are imposed by law but deny having breached such duties.
26 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
27 FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 87. Defendants state that this paragraph of the Complaint contains legal contentions to
5 which no response is required. To the extent that a response is deemed required, Defendants
6 admit that they had duties as are imposed by law but deny having breached such duties.
7 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
8 FDA-approved prescribing information. Defendants state that the potential effects of
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
12 the Complaint.

13 88. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
15 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
16 effective when used in accordance with its FDA-approved prescribing information. Defendants
17 state that the potential effects of Celebrex® were and are adequately described in its FDA-
18 approved prescribing information, which was at all times adequate and comported with
19 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
20 remaining allegations in this paragraph of the Complaint, including all subparts.

21 89. Defendants are without knowledge or information sufficient to form a belief as to the
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
23 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
24 effective when used in accordance with its FDA-approved prescribing information. Defendants
25 state that the potential effects of Celebrex® were and are adequately described in its FDA-
26 approved prescribing information, which was at all times adequate and comported with
27 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
28 remaining allegations in this paragraph of the Complaint.

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90. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

91. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

92. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical conditions and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

93. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

94. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

95. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Strict Liability

96. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'

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1 Complaint as if fully set forth herein.

2 97. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
4 Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of
5 time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
6 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
7 with their approval by the FDA. Defendants admit that, during certain periods of time,
8 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
9 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
10 providers who are by law authorized to prescribe drugs in accordance with their approval by the
11 FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and
12 consumers without substantial change from the time of sale. Defendants deny the remaining
13 allegations in this paragraph of the Complaint.

14 98. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny the remaining allegations in this paragraph of the Complaint.

19 99. Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the
24 remaining allegations in this paragraph of the Complaint.

25 100. Defendants state that Celebrex® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the
2 remaining allegations in this paragraph of the Complaint, including all subparts.

3 101. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
5 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
6 effective when used in accordance with its FDA-approved prescribing information. Defendants
7 state that the potential effects of Celebrex® were and are adequately described in its FDA-
8 approved prescribing information, which was at all times adequate and comported with
9 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
10 Celebrex® is defective, deny that Celebrex® caused Plaintiffs injury or damage, and deny the
11 remaining allegations in this paragraph of the Complaint.

12 102. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
17 remaining allegations in this paragraph of the Complaint.

18 103. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
20 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
21 effective when used in accordance with its FDA-approved prescribing information. Defendants
22 state that the potential effects of Celebrex® were and are adequately described in its FDA-
23 approved prescribing information, which was at all times adequate and comported with
24 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
25 Celebrex® is defective, deny that Celebrex® caused Plaintiffs injury or damage, and deny the
26 remaining allegations in this paragraph of the Complaint.

27 104. Defendants state that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
4 the Complaint.

5 105. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
7 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
12 Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this
13 paragraph of the Complaint.

14 106. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
19 the Complaint.

20 107. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
22 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
23 effective when used in accordance with its FDA-approved prescribing information. Defendants
24 state that the potential effects of Celebrex® were and are adequately described in its FDA-
25 approved prescribing information, which was at all times adequate and comported with
26 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
27 remaining allegations in this paragraph of the Complaint.

28 108. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or

1 damage, and deny the remaining allegations in this paragraph of the Complaint.

2 109. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
3 damage, and deny the remaining allegations in this paragraph of the Complaint.

4 110. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
5 damage, and deny the remaining allegations in this paragraph of the Complaint.

6 111. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
7 damage, and deny the remaining allegations in this paragraph of the Complaint.

8 **Response to Third Cause of Action: Breach of Express Warranty**

9 112. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
10 Complaint as if fully set forth herein.

11 113. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
13 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
14 effective when used in accordance with its FDA-approved prescribing information. Defendants
15 state that the potential effects of Celebrex® were and are adequately described in its FDA-
16 approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants admit that they provided FDA-approved
18 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in
19 this paragraph of the Complaint.

20 114. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
22 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
23 effective when used in accordance with its FDA-approved prescribing information. Defendants
24 state that the potential effects of Celebrex® were and are adequately described in its FDA-
25 approved prescribing information, which was at all times adequate and comported with
26 applicable standards of care and law. Defendants admit that they provided FDA-approved
27 prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and
28 deny the remaining allegations in this paragraph of the Complaint, including all subparts.

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115. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

116. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

117. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

118. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

119. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

120. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

121. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

1 122. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
2 damage, and deny the remaining allegations in this paragraph of the Complaint.

3 **Response to Fourth Cause of Action: Breach of Implied Warranty**

4 123. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
5 Complaint as if fully set forth herein.

6 124. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
7 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
8 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
9 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
10 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
11 Celebrex® in the United States to be prescribed by healthcare providers who are by law
12 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
13 the remaining allegations in this paragraph of the Complaint.

14 125. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants admit that they provided FDA-approved prescribing information regarding
19 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

20 126. Defendants state that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny the remaining allegations in this paragraph of the Complaint.

25 127. Defendants state that this paragraph of the Complaint contains legal contentions to
26 which no response is required. To the extent that a response is deemed required, Defendants
27 state that Celebrex® was and is safe and effective when used in accordance with its FDA-
28 approved prescribing information. Defendants state that the potential effects of Celebrex®

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1 were and are adequately described in its FDA-approved prescribing information, which was at
2 all times adequate and comported with applicable standards of care and law. Defendants deny
3 any wrongful conduct, deny that they breached any warranty, and deny the remaining
4 allegations in this paragraph of the Complaint.

5 128. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
7 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® is a prescription
8 medication which is approved by the FDA for the following indications: (1) for relief of the
9 signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid
10 arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of
11 primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial
12 adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance
13 surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the
14 signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older.
15 Defendants deny the remaining allegations in this paragraph of the Complaint.

16 129. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
18 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
19 effective when used in accordance with its FDA-approved prescribing information. Defendants
20 state that the potential effects of Celebrex® were and are adequately described in its FDA-
21 approved prescribing information, which was at all times adequate and comported with
22 applicable standards of care and law. Defendants admit that they provided FDA-approved
23 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in
24 this paragraph of the Complaint.

25 130. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
27 Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case,
28 Celebrex® was expected to reach users and consumers without substantial change from the

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1 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

2 131. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
4 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
5 effective when used in accordance with its FDA-approved prescribing information. Defendants
6 state that the potential effects of Celebrex® were and are adequately described in its FDA-
7 approved prescribing information, which was at all times adequate and comported with
8 applicable standards of care and law. Defendants deny any wrongful conduct, deny that they
9 breached any warranty, and deny the remaining allegations in this paragraph of the Complaint.

10 132. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
11 damage, and deny the remaining allegations in this paragraph of the Complaint.

12 133. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
13 damage, and deny the remaining allegations in this paragraph of the Complaint.

14 134. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
15 damage, and deny the remaining allegations in this paragraph of the Complaint.

16 135. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
17 damage, and deny the remaining allegations in this paragraph of the Complaint.

18 **Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment**

19 136. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
20 Complaint as if fully set forth herein.

21 137. Defendants state that this paragraph of the Complaint contains legal contentions to
22 which no response is required. To the extent that a response is deemed required, Defendants
23 admit that they had duties as are imposed by law but deny having breached such duties.
24 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
25 FDA-approved prescribing information. Defendants state that the potential effects of
26 Celebrex® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

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1 the Complaint.

2 138. Defendants state that Celebrex® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants state that the potential effects of
4 Celebrex® were and are adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
7 the Complaint, including all subparts.

8 139. Defendants state that Celebrex® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
13 the Complaint.

14 140. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
16 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
17 effective when used in accordance with its FDA-approved prescribing information. Defendants
18 state that the potential effects of Celebrex® were and are adequately described in its FDA-
19 approved prescribing information, which was at all times adequate and comported with
20 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
21 Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this
22 paragraph of the Complaint.

23 141. Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
28 the Complaint.

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1 142. Defendants are without knowledge or information sufficient to form a belief as to the
2 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
3 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
4 effective when used in accordance with its FDA-approved prescribing information. Defendants
5 state that the potential effects of Celebrex® were and are adequately described in its FDA-
6 approved prescribing information, which was at all times adequate and comported with
7 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
8 remaining allegations in this paragraph of the Complaint.

9 143. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
11 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
12 effective when used in accordance with its FDA-approved prescribing information. Defendants
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-
14 approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
16 remaining allegations in this paragraph of the Complaint.

17 144. Defendants are without knowledge or information sufficient to form a belief as to the
18 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
19 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
20 effective when used in accordance with its FDA-approved prescribing information. Defendants
21 state that the potential effects of Celebrex® were and are adequately described in its FDA-
22 approved prescribing information, which was at all times adequate and comported with
23 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
24 remaining allegations in this paragraph of the Complaint.

25 145. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
27 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

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1 state that the potential effects of Celebrex® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
4 remaining allegations in this paragraph of the Complaint.

5 146. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
7 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
12 remaining allegations in this paragraph of the Complaint.

13 147. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
15 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
16 effective when used in accordance with its FDA-approved prescribing information. Defendants
17 state that the potential effects of Celebrex® were and are adequately described in its FDA-
18 approved prescribing information, which was at all times adequate and comported with
19 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
20 remaining allegations in this paragraph of the Complaint.

21 148. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
22 damage, and deny the remaining allegations in this paragraph of the Complaint.

23 149. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
24 damage, and deny the remaining allegations in this paragraph of the Complaint.

25 150. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
26 damage, and deny the remaining allegations in this paragraph of the Complaint.

27 151. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
28 damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Sixth Cause of Action: Unjust Enrichment

152. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

153. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

154. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

155. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

156. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

157. Defendants are without knowledge or information sufficient to form a belief as to the

1 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
 2 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
 3 effective when used in accordance with its FDA-approved prescribing information. Defendants
 4 state that the potential effects of Celebrex® were and are adequately described in its FDA-
 5 approved prescribing information, which was at all times adequate and comported with
 6 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
 7 remaining allegations in this paragraph of the Complaint.

8 158. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
 9 damage, and deny the remaining allegations in this paragraph of the Complaint.

10 **Response to Seventh Cause of Action:**

11 **State Consumer Fraud and Deceptive Trade Practices Act**

12 158. Answering the second Paragraph 158 of this Complaint, Defendants incorporate by
 13 reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

14 159. Plaintiffs' Complaint omits Paragraph Number 159.

15 160. Defendants state that this paragraph of the Complaint contains legal contentions to
 16 which no response is required. To the extent that a response is deemed required, Defendants
 17 admit that they had duties as are imposed by law but deny having breached such duties.
 18 Defendants deny the remaining allegations in this paragraph of the Complaint.

19 161. Defendants are without knowledge or information sufficient to form a belief as to the
 20 truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the
 21 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
 22 with its FDA-approved prescribing information. Defendants state that the potential effects of
 23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
 24 which was at all times adequate and comported with applicable standards of care and law.
 25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
 26 the Complaint.

27 162. Defendants are without knowledge or information sufficient to form a belief as to the
 28 truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the

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1 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
6 damage, and deny the remaining allegations in this paragraph of the Complaint.

7 163. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the
9 same. Defendants deny the remaining allegations in this paragraph of the Complaint.

10 164. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the
12 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
17 the Complaint.

18 165. Defendants state that this paragraph of the Complaint contains legal contentions to
19 which no response is required. To the extent that a response is deemed required, Defendants
20 deny any wrongful conduct and deny the remaining allegations in this paragraph of the
21 Complaint.

22 166. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
23 damage, and deny the remaining allegations in this paragraph of the Complaint.

24 167. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
25 damage, and deny the remaining allegations in this paragraph of the Complaint.

26 168. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
27 damage, and deny the remaining allegations in this paragraph of the Complaint.

28 169. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or

1 damage, and deny the remaining allegations in this paragraph of the Complaint.

2 170. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
3 damage, and deny the remaining allegations in this paragraph of the Complaint.

4 171. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
5 damage, and deny the remaining allegations in this paragraph of the Complaint.

6 **Response to Prayer For Relief**

7 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
8 damage, and deny the remaining allegations in paragraph of the Complaint headed “Prayer for
9 Relief,” including all subparts.

10 **III.**

11 **GENERAL DENIAL**

12 Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs’
13 Complaint that have not been previously admitted, denied, or explained.

14 **IV.**

15 **AFFIRMATIVE DEFENSES**

16 Defendants reserve the right to rely upon any of the following or additional defenses to
17 claims asserted by Plaintiffs to the extent that such defenses are supported by information
18 developed through discovery or evidence at trial. Defendants affirmatively show that:

19 **First Defense**

20 1. The Complaint fails to state a claim upon which relief can be granted.

21 **Second Defense**

22 2. Celebrex® is a prescription medical product. The federal government has preempted
23 the field of law applicable to the labeling and warning of prescription medical products.
24 Defendants’ labeling and warning of Celebrex® was at all times in compliance with applicable
25 federal law. Plaintiffs’ causes of action against Defendants, therefore, fail to state a claim upon
26 which relief can be granted; such claims, if allowed, would conflict with applicable federal law
27 and violate the Supremacy Clause of the United States Constitution.

1 **Third Defense**

2 3. At all relevant times, Defendants provided proper warnings, information and
3 instructions for the drug in accordance with generally recognized and prevailing standards in
4 existence at the time.

5 **Fourth Defense**

6 4. At all relevant times, Defendants' warnings and instructions with respect to the use of
7 Celebrex® conformed to the generally recognized, reasonably available, and reliable state of
8 knowledge at the time the drug was manufactured, marketed and distributed.

9 **Fifth Defense**

10 5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the
11 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

12 **Sixth Defense**

13 6. Plaintiffs' action is barred by the statute of repose.

14 **Seventh Defense**

15 7. Plaintiffs' claims against Defendants are barred to the extent Plaintiffs were
16 contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and
17 any recovery by Plaintiffs should be diminished accordingly.

18 **Eighth Defense**

19 8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or
20 omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the
21 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not
22 liable in any way.

23 **Ninth Defense**

24 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,
25 intervening causes for which Defendants cannot be liable.

26 **Tenth Defense**

27 10. Any injuries or expenses incurred by Plaintiffs were not caused by Celebrex®, but were
28 proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act

of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiff’s treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiffs’ causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiffs’ alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendants and any liability of Defendants is therefore barred.

Seventeenth Defense

17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

Nineteenth Defense

19. Plaintiffs knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

Twenty-third Defense

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable

1 federal laws, regulations, and rules.

2 **Twenty-fifth Defense**

3 25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate
4 "direction or warnings" as to the use of the subject pharmaceutical product within the meaning
5 of Comment j to Section 402A of the Restatement (Second) of Torts.

6 **Twenty-sixth Defense**

7 26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim
8 because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of
9 Restatement (Second) of Torts § 402A, Comment k.

10 **Twenty-seventh Defense**

11 27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical
12 product at issue "provides net benefits for a class of patients" within the meaning of Comment f
13 to § 6 of the Restatement (Third) of Torts: Products Liability.

14 **Twenty-eighth Defense**

15 28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts:
16 Products Liability.

17 **Twenty-ninth Defense**

18 29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead
19 facts sufficient under the law to justify an award of punitive damages.

20 **Thirtieth Defense**

21 30. Defendants affirmatively aver that the imposition of punitive damages in this case
22 would violate Defendants' rights to procedural due process under both the Fourteenth
23 Amendment of the United States Constitution and the Constitutions of the States of North
24 Dakota and California, and would additionally violate Defendants' rights to substantive due
25 process under the Fourteenth Amendment of the United States Constitution.

26 **Thirty-first Defense**

27 31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and
28 Fourteenth Amendments to the United States Constitution.

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Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiffs' punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiffs failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of North Dakota and California. Any

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law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiffs.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and

any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Celebrex® even if the product labeling contained the information that Plaintiffs contend should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs.

Fifty-second Defense

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiffs' claims are preempted by the

Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendants state on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation as may apply.

Fifty-sixth Defense

56. Defendants state on information and belief that any injuries, losses, or damages suffered by Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiffs' recovery against Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

Fifty-seventh Defense

57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

Fifty-eighth Defense

58. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiffs take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;

3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiffs' alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiffs' injuries and damages; and
6. That Defendants have such other and further relief as the Court deems appropriate.

January 14, 2008

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CORPORATION, and G.D. SEARLE
LLC

JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

January 14, 2008

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